IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

PLANNED PARENTHOOD CINCINNATI REGION, *et al.*,	:	Case No. C-1-04-493
Plaintiffs,	:	District Judge Susan J. Dlott
v.	:	ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND ENJOINING DEFENDANTS
BOB TAFT, *et al.*,	:	
Defendants.	:	

This matter comes before the Court on remand from the United States Court of Appeals for the Sixth Circuit and on Plaintiffs' Motion for Summary Judgment and Permanent Injunction or, in the Alternative, Renewed Motion for Preliminary Injunction ("SJ Motion") (doc. #69). For the reasons that follow, the Court **GRANTS** Plaintiffs' Motion for Summary Judgment and Permanent Injunction or, in the Alternative, Renewed Motion for Preliminary Injunction ("SJ Motion") (doc. #69) and **PERMANENTLY ENJOINS** Defendants from enforcing any provisions of Ohio's H.B. 126 ("the Act").

I. PROCEDURAL HISTORY & BACKGROUND

Plaintiffs filed both their original Complaint (doc. #1) and their original Motion for Preliminary Injunction ("PI Motion") (doc. #2) on August 2, 2004, and filed an Amended Complaint on September 13, 2004 (doc.#18). On September 22, 2004, this Court entered its

Order granting Plaintiffs' motion for a preliminary injunction (docs. ## 26 and 41).[1] On September 22, 2004, Defendants filed an interlocutory appeal of this Court's order. On February 15, 2006, the Sixth Circuit issued its Opinion affirming in part and vacating in part this Court's Order granting the preliminary injunction, and remanded the case to this Court to determine the appropriate scope of preliminary injunctive relief in light of the Sixth Circuit's opinion. (See doc. #60.) On April 13, 2006, the Sixth Circuit issued an amended judgment to the same effect. (Doc. #66); see also Planned Parenthood Cincinnati Region v. Taft, 444 F.3d 502, 505 (6th Cir. 2006).

On March 16, 2006, this Court set a schedule for the parties' remand briefing regarding the scope of the preliminary injunction. (See doc. # 63.) Instead of limiting their briefing to the scope of the preliminary injunction, however, Plaintiffs filed the instant consolidated SJ Motion requesting both summary judgment and a permanent injunction, or, only in the alternative, a renewed preliminary injunction which, as before, enjoins the entire Act. The Court held oral argument on that Motion on June 26, 2006.

A. The Parties

Plaintiffs in this case are Planned Parenthood Southwest Ohio Region[2], Planned Parenthood of Central Ohio, Planned Parenthood of Greater Cleveland, and Preterm (collectively

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1 On October 2, 2004, the Court issued an Amended Order correcting a typographical error in the original Order. (See Doc. #41.)

2 Plaintiff Planned Parenthood Southwest Ohio Region was previously named Planned Parenthood Cincinnati Region. The Complaint was filed in the entity's former name, but this Court has since received plaintiff's Notice of Change in Plaintiff's Name (doc. #49).

"Planned Parenthood"), and Doctors Sogor and Kade ("Plaintiff Physicians") on behalf of themselves and their patients (all collectively, "Plaintiffs"). Defendants are Bob Taft, the Governor of Ohio, and Jim Petro, the Attorney General of Ohio, in their official capacities, and Joseph Deters,[3] as Prosecuting Attorney for Hamilton County, Ohio, and as a representative of a class of all prosecuting attorneys in Ohio (collectively, "Defendants").[4]

B. The Challenged Act

Plaintiffs brought this action challenging the constitutionality of the Act, which was to take effect on September 23, 2004. The Act regulates the use of mifepristone, commonly known as RU-486, which is a drug used for medical abortion. Specifically, the Act provides:

> No person shall knowingly give, sell, dispense, administer, otherwise provide, or prescribe RU-486 (mifepristone) to another for the purpose of inducing an abortion . . . unless the person . . . is a physician, the physician satisfies all the criteria established by federal law that a physician must satisfy in order to provide RU-486 (mifepristone) for inducing abortions, and the physician provides the RU-486 (mifepristone) to the other person for the purpose of inducing an abortion *in accordance with all provisions of federal law* that govern the use of RU-486 (mifepristone) for inducing abortions.

§ 2919.123(A) (emphasis added). The Act defines "federal law" as, "any law, rule, or regulation of the United States or any drug approval letter of the Food and Drug Administration of the

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3 Pursuant to Federal Rule of Civil Procedure 25(d), Plaintiffs moved for and were granted leave to substitute the newly elected Hamilton County Prosecutor, Joseph Deters, for the originally named Defendant Prosecutor Michael Allen (docs. ## 48,51).

4 On August 23, 2004, Plaintiffs filed a Motion for Certification of Defendant Class (doc. #10), requesting that the Court certify a defendant class consisting of all county prosecuting attorneys in Ohio and appoint Michael K. Allen as the defendant class representative. This Court certified that Defendant Class on December 1, 2004. (See doc. #46).

United States that governs or regulates the use of RU-486 (mifepristone) for the purpose of inducing abortions." See § 2919.123(F)(1).

The Act provides that those who violate its provisions are guilty of a felony (of varying degrees) and requires state licensing boards to discipline doctors who enter a plea of guilty to or are found guilty of violating the law. Specifically, violators of the Act are deemed "guilty of unlawful distribution of an abortion-inducing drug, a felony of the fourth degree," and repeat offenders are guilty of a felony in the third degree. See § 2919.123(E). Further, the Act provides that offenders who are doctors are "subject to sanctioning as provided by law by the regulatory or licensing board or agency that has the administrative authority to suspend or revoke the offender's professional license." Id. Finally, the Act requires the state medical board to revoke, suspend, reprimand, or refuse to grant a certificate to any doctor who enters a plea of guilty or is found guilty of violating any state law regulating the distribution of any drug. See § 4731.22(B)(3). Section 4731.22(B)(3) clearly applies to doctors found guilty of violating Section 2919.123(A) for unlawfully prescribing mifepristone.

C. Plaintiffs' Original Motion for a Preliminary Injunction

Originally, Plaintiffs moved for a preliminary injunction "restraining defendants, their employees, agents, and successors, and all others acting in concert or participation with them, from enforcing the provisions of H.B. 126." (See doc. #2 at 1). Plaintiffs challenged the Act on the following grounds: "the Act is unconstitutionally vague; the Act violates their patients' right to bodily integrity by compelling surgery in circumstances where a medical abortion [via mifepristone, and as opposed to surgical abortion] would otherwise be the desired or appropriate treatment; the Act lacks the constitutionally-mandated exception to allow otherwise restricted

practices where they are necessary to preserve a woman's life or health; and, the Act imposes an undue burden on their patients' right to choose abortion by prohibiting a safe and common method of pre-viability abortion." (See doc. #2, at 1.)

In ruling on Plaintiff's PI Motion, this Court described Plaintiffs' arguments as follows[5]: "Plaintiffs allege that because of the former factors [see supra former paragraph], Plaintiffs have a strong likelihood of success on the merits. Further, Plaintiffs allege that Planned Parenthood, Plaintiff Physicians, and their patients would face irreparable injury if the Act takes effect. (Id. at 18-19.) Specifically, Plaintiffs argue that because the Act is unconstitutionally vague, Plaintiff Physicians would be left to guess about whether they may legally provide medical abortions in certain instances. (Id. at 18.) Specifically, Plaintiffs state that Planned Parenthood and the Plaintiff Physicians have been providing medical abortions using an evidence-based protocol of mifepristone.[6] (See doc. #18, ¶¶ 6-11.) This evidence-based protocol differs in several respects from the protocol which the FDA tested and on which it based its approval of mifepristone ["FDA-approved protocol"], including the dose of mifepristone and the dose and administration of its companion drug, misoprostol, and also allows for a medical abortion later in the term of pregnancy.[7] Plaintiffs note that the Act provides that physicians may prescribe

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5 The following recitation of Plaintiffs' arguments for a preliminary injunction is excerpted from this Court's Order granting Plaintiff's motion for a preliminary injunction (doc. #41-2.)

6 Or in the case of Planned Parenthood of Central Ohio, intended to switch to an evidence-based protocol, but suspended those preparations due to uncertainty regarding the meaning of the Act. (See doc. # 18, ¶ 8.)

7 The evidence-based protocol for medical abortion [that Planned Parenthood and Plaintiff Physicians used at the time of the PI Motion] consists of a single oral dose of 200 mg of

mifepristone only in accordance with federal law, and that the Act includes the FDA approval letter within its definition of federal law. However, Plaintiffs also note that the FDA approval letter does not require physicians to adhere to any particular protocol, although the documents on the final printed labeling do discuss only the protocol that was tested by the FDA. (Id. at ¶ 38.) Thus, Plaintiffs argue that it is unclear whether the Act's inclusion of the FDA approval letter in the definition of federal law renders it illegal for a physician to prescribe the evidence-based protocol of mifepristone. Consequently, Plaintiffs argue that Plaintiff Physicians would face the threat of possible criminal prosecution and loss or suspension of their medical licenses if they continue to prescribe the evidence-based protocol of mifepristone. (Id. at ¶ 53.) Plaintiffs also argue that Plaintiff Physicians' patients would face irreparable harm because the Act may force some women seeking an abortion to forego medical abortion and undergo either surgical abortion or other more invasive procedures, which may be both riskier and more costly for a particular woman. (See doc. # 2, at 18-19.)" (See doc. #41-2 at 8-9.)

This Court held that Plaintiffs had demonstrated a strong likelihood of success on the merits of their claimed violation of their constitutional rights on two alternative grounds: 1) the Act lacked any health exception, which this Court construed as a per se requirement under Supreme Court precedent for statutes regulating abortion; and 2) evidence presented at the

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mifepristone followed by a single dose of .8 mg misoprostol administered vaginally, and is effective for medical abortion through at least 63 days after a woman's last menstrual period ("LMP"). The protocol for medical abortion that the FDA tested and on which it based its approval of mifepristone consisted of three oral doses of 200 mg of mifepristone followed by a single dose of .4 mg misoprostol also taken orally, through 49 days LMP. [Planned Parenthood now offers two variations of their former evidence-based protocol. (Doc. #69 at 6 n.5.) For the purposes of this memorandum, the court will not distinguish between the different evidence-based protocols and will use the same term, "evidence-based protocol," to refer to all of them.]

hearing on the PI Motion demonstrated that there were women for whom the evidence-based protocol for medical abortion was safer than surgical abortion. (Id. at 10-11.) Having so found, the Court also found that the other factors to be considered for a preliminary injunction necessarily weighed in its favor. (Id. at 12-13.) The Court therefore entered an order enjoining Defendants from enforcing any provisions of the Act. (Id. at 13.)

D. The Sixth Circuit's Decision on Appeal

On appeal, the Sixth Circuit held that this Court erred in holding that all statutes regulating abortion, including the Act, must contain a per se health exception. The Sixth Circuit described the proper legal standard as follows:

> where substantial medical authority supports the proposition that banning a particular abortion procedure could endanger women's health *Casey* requires the statute to include a health exception when the procedure is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother. An exception is constitutionally necessary where substantial medical authority indicates that a banned procedure would be safer than the other available procedures, not just when banning the procedure subjects a woman to risks from the pregnancy itself. As emphasized previously by this circuit, an exception is only necessary (and must only cover) circumstances where a statute poses a *significant* health risk. Finally, an adequate showing of a significant health risk in certain circumstances is sufficient to require an exception even if those circumstances rarely occur.

Planned Parenthood Cincinnati Region, 444 F.3d at 511.

The Sixth Circuit held that, despite having misread the law, this Court was nevertheless correct to enjoin the Act because "[a]t the [PI Motion] evidentiary hearing Plaintiffs introduced expert testimony from two doctors which established that, if enforced, the statute would result in significant risk to women's health in particular, albeit narrow, circumstances." Id. at 511. The

Sixth Circuit concluded that "the evidence presented to the district court established at least as persuasive a case as that presented in *Carhart* that the abortion regulation at issue could pose a significant health risk to women with particular medical conditions. Consequently, the district court's ruling that Plaintiffs established a strong likelihood of prevailing on the merits has not been shown to be erroneous." Id. at 514.

The Sixth Circuit thus remanded the case to this Court "for consideration of the appropriate scope of injunctive relief in light of the United States Supreme Court's recent decision in *Ayotte v. Planned Parenthood of Northern New England*, --- U.S. ----, 126 S.Ct. 961, 163 L.Ed.2d 812 (2006)." In Ayotte, the Supreme Court held that "[g]enerally speaking, when confronting a constitutional flaw in a statute, we try to limit the solution to the problem. We prefer, for example, to enjoin only the unconstitutional applications of a statute while leaving other applications in force, or to sever its problematic portions while leaving the remainder intact." Ayotte, 126 S.Ct at 967. The Sixth Circuit clarified that in light of Ayotte, this Court should "leav[e] the preliminary injunction undisturbed insofar as it prohibits unconstitutional applications of the statute." It also held that "[o]n remand, the district court must determine whether a broader injunction is still required by considering the legislative intent and the Plaintiffs' as-yet-unaddressed vagueness, bodily integrity, and undue burden claims." Planned Parenthood Cincinnati Region, 444 F.3d at 517.

On remand, however, Plaintiffs seek either summary judgment and a *permanent* injunction of the Act for unconstitutional vagueness, or, in the alternative, a renewed preliminary injunction based on its other constitutional arguments that enjoins the entire Act. The self-dubbed State Defendants (Attorney General Petro and Governor Robert Taft) filed a

Memorandum in Opposition to Plaintiff's SJ Motion (doc. #74), which Defendant Deters joined on behalf of himself and the other Defendant County Prosecuting Attorneys (see doc. #76).

II. JURISDICTION

This Court has federal question jurisdiction to consider a case, such as this one, where the plaintiffs challenge an alleged deprivation of a Constitutional right by a State law. See 28 U.S.C. §§ 1331, 1343(a)(3), and 1343(a)(4).

III. PLAINTIFF'S SJ MOTION

A. Motion for Summary Judgment

Plaintiffs move for summary judgment on their claim that the Act is impermissibly vague and thereby violates Plaintiffs' right to due process under the Fourteenth Amendment. If this Court grants summary judgment to Plaintiffs, they also request that the Court permanently enjoin the Act.

1. Legal Standard

Summary judgment is appropriate if no genuine issues of material fact exist and the moving party is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c). On a motion for summary judgment, the movant has the burden of showing that no genuine issue of material facts are in dispute, and the Court must read the evidence, together with all inferences that can permissibly be drawn therefrom, in the light most favorable to the party opposing the motion. See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 585-87 (1986).

The moving party may support a motion for summary judgment with affidavits or other proof or by exposing the lack of evidence on an issue for which the nonmoving party will bear

the burden of proof at trial. See Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). In responding to a summary judgment motion, the nonmoving party may not rest upon the pleadings but must go beyond the pleadings and "present affirmative evidence in order to defeat a properly supported motion for summary judgment." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 257 (1986). The nonmoving party "must set forth specific facts showing there is a genuine issue for trial." Fed. R. Civ. Pro. 56(e). The task of the Court is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Liberty Lobby, 477 U.S. at 249. A genuine issue for trial exists when the evidence is not "so one-sided that one party must prevail as a matter of law." Id. at 252.

2. Analysis

a. Plaintiffs' Argument that the Act is Unconstitutionally Vague

The question of whether the Act is unconstitutionally vague is a question of law and therefore can be resolved on summary judgment. See U.S. v. Namey, 364 F.3d 843, 844 (6th Cir. 2004).

"It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." Grayned v. City of Rockford, 408 U.S. 104, 108 (1972). As the Grayned court explains:

> Vague laws offend several important values. First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning. Second, if arbitrary and discriminatory enforcement is to be prevented, laws must provide explicit standards for those who apply them. A vague law impermissibly delegates basic policy matters to policemen, judges, and juries for

> resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application.

Id. at 108-09 (1972). Thus, the Due Process clause of the Fourteenth Amendment prohibits laws so vague that persons of ordinary intelligence must guess at their meaning. See Smith v. Goguen, 415 U.S. 566, 573 n.8 (1974) (citations omitted). Also, "[t]he [vagueness] doctrine incorporates notions of fair notice or warning. Moreover, it requires legislatures to set reasonably clear guidelines for law enforcement officials and triers of fact in order to prevent 'arbitrary and discriminatory enforcement.'" Id. at 572-73.

Significantly, criminal statutes that implicate the exercise of constitutionally protected rights are subject to a more stringent vagueness test. See Colautti v. Franklin, 439 U.S. 379, 386, 391 (1979); Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 499 (1982). The Supreme Court has held that "the right of privacy, implicit in the liberty secured by the Fourteenth Amendment 'is broad enough to encompass a woman's decision whether or not to terminate her pregnancy.'" Collautti, 439 U.S. at 386 (citing Roe v. Wade, 410 U.S. 113, 153 (1973)). Thus, the Act, which implicates the exercise of that constitutionally protected right, is subject to a more stringent vagueness test.

First, in their SJ Motion, Plaintiffs argue that the Act violates their due process rights because it is unconstitutionally vague on its face. Plaintiffs argue that the undefined and ambiguous terms render the Act unconstitutionally vague. Specifically, Plaintiffs argue that

> It is unclear from the face of the Act what is meant by the requirements that physicians who provide mifepristone to induce medication [sic] abortion comply with "all criteria established by federal law" and [act] in accordance with "all provisions of federal law that govern use" of the drug. It is also unclear whether these requirements differ in any way from the requirements that the

> physicians satisfy "all the *specified* criteria established by federal law" and that the physicians provide mifepristone in accordance with "the *specified* provisions of federal law."

Doc. #69 at 7 (emphasis in original). Plaintiffs note that the Act does not define nor distinguish the terms "criteria," "specific criteria," provisions," and "specific provisions," each of which modifies the defined term "federal law." As Plaintiffs point out, in construing statutory language, "significance and effect should, if possible, be accorded to every word, phrase, sentence and part of an act." See Sarmiento v. Grange Mut. Cas. Co., 835 N.E.2d 692, 698 (Ohio 2005). Plaintiffs argue that because the Act fails to define these different modifying terms, it is thus "unclear from the face of the Act what is meant by the requirements that physicians who provide mifepristone to induce medication abortion comply with '*all criteria established by* federal law,' and in accordance with '*all provisions of* federal law that govern use' of the drug," as well as what it means for a physician to satisfy "*all the specified criteria* established by federal law," and provide mifepristone only in accordance with "*the specified provisions* of federal law." (Doc. #69 at 7 (emphasis added).) Plaintiffs conclude that "[t]hese vague and uncertain terms fail to give fair notice of what the Act proscribes and leave the door open for arbitrary and discriminatory enforcement of the Act," (id. at 7-8) thereby violating Plaintiffs' due process rights.

The Court agrees that the statute provides no bases for distinguishing between these phrases or knowing in what way they modify the Act's definition of federal law. The Act's vague terms are particularly troubling because they modify "federal law," the defined term with which physicians must comply or face criminal penalty.

Second, in their Reply, Plaintiffs make an even more persuasive argument that the Act is vague. Plaintiffs argue that Defendants' counterarguments regarding the plain meaning of the Act further reveal and compound the Act's vagueness. (Doc. #74 at 14-15.)[8] To address Plaintiffs' persuasive rebuttal, the Court must first address Defendants' counterargument.

In their Opposition to Plaintiffs SJ Motion, Defendants argue that the act is not vague and that from the Act's "plain language," it is clear that the Act prohibits physicians from prescribing the evidence-based protocol. Specifically, Defendants assert that it is clear that the Act "restricts the use of mifepristone to induce abortions in Ohio to the FDA approved indications and treatment regimen, as set forth in the approval letter and [the final printed labeling instructions ("FPL")]." (Doc. #74 at 2.) At another point in their Opposition, Defendants contend that in addition to the approval letter and "the *exact form* of the FPL, including the package insert, the Medication Guide, the Patient Agreement, and the Prescriber's Agreement, are clearly made a part of the approval of the drug" and therefore also part of the definition of federal law with which physicians must comply. (Id. at 15 (emphasis added).) In sum, Defendants argue that 1) by including the FDA approval letter in its definition of federal law, the Act also incorporates by reference into that definition the requirements of all of the documents referred to in the Approval

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8 Plaintiffs also argue that Defendants' interpretation of the Act "would require the Court to read language into the Act that does not appear in its text." (Doc. #77 at 6.) Plaintiffs cite Vought Indus., Inc. v. Tracy, 648 N.E. 2d 1364 (Ohio 1995), for the proposition that "'[t]here is no authority under any rule of statutory construction to add to, enlarge, supply, expand, extend or improve the provisions of the statute to meet a situation not provided for.'" (Id. at 7 (citing Vought, 648 N.E. 2d at 1367).) And, Plaintiffs argue that the legislative history does not support Defendants' construction of the Act. Plaintiffs conclude that for all of these reasons, it would be improper for this Court to accept Defendants' construction of the statute. The Court need not consider Plaintiffs' alternative arguments as it finds Defendants' counterarguments regarding the Act's plain meaning to be unavailing.

Letter (such as the FPL) and some of the documents that *those* documents refer to; and 2) the Approval Letter clearly limits physicians to prescribing FDA-approved protocol, and hence, so does the Act.

First, in rebutting Defendants' argument, Plaintiffs argue that it is far from clear that the Act's definition of federal law includes the FPL. As Plaintiffs point out, while the Act's definition of federal law specifically mentions the FDA approval letter, the Act itself does not. Thus, from the face of the Act (in its definition of federal law), there is no reason to believe that the Act includes the FPL as part of federal law with which physicians must comply. As Defendants argue, however, because the approval letter, which within the Act's definition of federal law, references the FPL, arguably, the FPL and other documents which the approval letter mentions are incorporated by reference into the Act's definition of federal law by reference.

The Court finds however, that even if it were clear from the face of the Act that the FPL is part of the definition of federal law – which it is not -- it is still not clear either what the approval letter requires regarding the FPL or what the FPL itself requires regarding acceptable dosage protocols. Most notably, it is unclear from the text of the approval letter whether, as Defendants submit, it mentions the FPL to limit physicians' prescription of mifepristone to the FDA-approved protocol. The approval letter states in relevant part that "[t]he final printed labeling (FPL) . . . must be identical to the submitted draft labeling . . . submitted September 27, 2000." (JX2.) The approval letter further provides that "[m]arketing the product with FPL that is not identical to the approved labeling text *may* render the product misbranded and an unapproved new drug." (Id.) Thus, while the approval letter mentions the FPL, it seems to do so

only to regulate the conduct of manufacturers and distributors of mifepristone, not physicians who prescribe mifepristone. On the other hand, the approval letter also states that "[t]his new drug application provides for the use of [mifepristone] for the medical termination of intrauterine pregnancy through 49 days' pregnancy. We have . . . concluded that adequate information has been presented to approve [mifespristone] [t]ablets, 200 mg, for use as recommended in the agreed upon labeling text." The former language could indeed be read to limit physicians' prescription of mifepristone to the FDA-approved protocol, but it is far from clear that it does so. And, as Plaintiffs point out, neither the former language, nor any other language in the approval letter, nor the Act itself, nor the Food and Drug Act *specifically prohibits* physicians from prescribing an evidence-based protocol of mifepristone. (See JX1, JX2 and JX9.) Thus, the Act is unconstitutionally vague because it is unclear whether 1) the Act's definition of federal law incorporates the FPL, and 2) if it does, what that incorporation means in terms of lawful prescription of mifepristone.

Second, in arguing that Defendants' reading of the Act underscores its vagueness, Plaintiffs point out that under Defendants' reading of the statute, physicians may only prescribe mifepristone in accordance with the FPL, as well as "*the* approved indication, treatment regimen, and distribution *restrictions set forth in the FDA Approval Letter* ***and the materials incorporated therein***." (Doc. #69 at 13, citing Defs. Resp (doc. # 74) at 6 (emphasis added).) Plaintiffs point out that this reading arguably also requires physicians to adhere to the requirements of more than 90 separate documents that were submitted to the FDA as part of the approval process, as well as numerous federal regulations, all of which are referred to in the approval letter.[9] (Doc. #69 at

9 Defendants argue that those 90-plus separate documents are clearly *not* intended to be considered part of the Act's definition of federal law because all the approval letter does is

13.) Plaintiffs argue further that under the State's reading of the Act, "all of these [90-plus] documents and regulations could potentially be construed as 'materials incorporated therein,' thereby becoming requirements subject to criminal prosecution under the Act.'" (Id.) Moreover, Plaintiff notes that many of these materials – including the approval letter itself, the FPL, and the Mifeprex package insert, medication guide, and patient agreement, which are all specifically mentioned in the approval letter – have been revised or reissued since the FDA issued its initial approval letter. (*Compare* JX 2 *and* JX 9; JX 3-6 *and* JX 10-12.) Plaintiffs submit that under Defendants' reading of the Act, it is unclear with which of the referenced documents, and with which *version* of those documents, physicians are required to comply under the Act. Plaintiffs conclude that Defendants' reading of the Act, if accepted, would place Plaintiffs "in the untenable position of not knowing which statements contained in this voluminous series of documents they are bound to follow in order to avoid facing criminal prosecution." (Id.) Plaintiffs conclude that Defendants' reading of the Act is further evidence of its vagueness.

The Court agrees with Plaintiffs. As Plaintiffs point out, under Defendants' reading of the Act, the Act's requirements and prohibitions could change over time, without any action by the legislature to change the language of the Act itself. In response to this criticism, Defendants argue that because the physicians whose conduct it regulates, "practice in a very particularized area of medicine," they "can certainly be expected to be familiar with the prescribing

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"'acknowledge receipt'" of those documents. (See doc. #74 at 14-15.) Defendants' argument is inconsistent with their argument that the Act's reference to the approval letter incorporates by reference the FPL, the package insert, the Medication Guide, the Patient Agreement, and the Prescriber's Agreement. The approval letter's reference to those 90-plus documents that they received and reviewed in approving mifepristone arguably does incorporate the contents and requirements of those documents into the FDA approved regimen.

information about mifepristone, including the FDA approved indications and regimen." (See doc. #74 at 17.) Defendants cite Fleming v. U.S. Dept. of Ag., 713 F.2d 179, 184 (6th Cir. 1983), for the principle that "when the persons affected by the regulation[] are a select group with specialized understanding of the subject being regulated the degree of definiteness required to satisfy due process concerns is measured by the common understanding and commercial knowledge of the group." (See doc. #74 at 17 (quoting Fleming, 713 F.2d at 184).) Although Defendants' citation is correct, their argument misses the point. The question here is not, as Defendants suggest, whether physicians regulated by the Act are able to understand "the prescribing information for mifepristone, including the FDA approved indications and regimen." (See doc. #74 at 17.) Rather, the question is whether such physicians can understand whether, under the Act's definition of federal law, they must prescribe mifepristone only according to the FDA-approved protocol or whether they may lawfully prescribe an evidence-based protocol.

Plaintiffs argue that for all of the above reasons, Defendants' reading of the Act renders it more variable -- and thus vaguer – over time. The Court agrees. Defendants' interpretation of the Act does render the Act all the more uncertain. What is most significant, however, is that Defendants' interpretation of the Act, particularly in terms of its incorporation by reference of the FPL in the definition of federal law, is tenable. That is to say, the parties' briefs demonstrate that the Act is susceptible to *at least* two equally good faith and plausible, but contradictory, legal interpretations. Thus, the Act fails "to set reasonably clear guidelines for law enforcement officials and triers of fact," and thereby risks "'arbitrary and discriminatory enforcement.'" See Goguen, 415 U.S. at 573. Moreover, given this Court's own struggle in divining the meaning of the Act, as well as that of the parties' highly competent lawyers, the Court is convinced that the

physicians regulated by the Act, untrained in the law, could not possibly be expected to understand its requirements and prohibitions. Thus, the Act fails to give those subject to criminal punishment under the Act a "reasonable opportunity to know what is prohibited."[10] See Grayned, 408 U.S. at 108, and therefore fails to provide fair notice. See id. Because the Act fails to meet either major due process requirement, the Court holds that the Act is unconstitutionally vague.

b. **Defendants' Alternative Argument Regarding the Act's "Knowingly" Requirement**

Defendants argue that, even if the Court finds, as it has, that the Act is unconstitutionally vague, the Act's "knowingly" requirement cures the Act's vagueness. Defendants cite Village of Hoffman Estates for the principle that a scienter requirement "mitigates a law's vagueness, especially with respect to the adequacy of notice to the complainant that his conduct is proscribed." (Doc. #74 at 20 (citing Village of Hoffman Estates, 455 U.S. at 499).)

Although Defendants are correct that the Act includes a scienter requirement, their argument is nonetheless unavailing. The Act provides, in relevant part, that:

> A person who gives, sells, dispenses, administers, otherwise provides or prescribes RU-486 (mifepristone) to another as described in division (A) of this section **shall not be prosecuted** based on a violation of the criteria contained in this division **unless the person knows** that . . . the person did not satisfy all the specified criteria established by federal law, or that the person did not provide the RU-486 (mifepristone) in accordance with the specified provisions of federal law, whichever is applicable.

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10 The Court notes that Defendants' interpretation, which would permit the Act's requirements and prohibitions to change without any amendment to the Act or notice to the physicians it regulates, is particularly troublesome from a fair warning perspective.

§ 2919.123(A) (emphasis added). As highlighted above, the Act conditions a violator's prosecution on his knowledge that he failed to satisfy the specified criteria of federal law or that he did not provide mifepristone in accordance with the specified provisions of federal law.

However, the Act's scienter requirement is irrelevant because it is dependent upon the vague term "federal law." Contrary to Defendants' assertion, Village of Hoffman Estates provides only that "a scienter requirement *may* mitigate a law's vagueness." Village of Hoffman Estates, 455 U.S. at 499 (emphasis added).) As Plaintiffs point out, "a scienter requirement applied to an element that is itself vague does not cure the provision's overall vagueness." See, e.g., Planned Parenthood Federation of Am., Inc. v. Gonzales, 435 F.3d 1163, 1184 (9th Cir. 2006). Here, the Act's knowingly requirement does just that: it applies to the vague definition of federal law. As this Court has held that the Act is unconstitutionally vague due to its uncertain definition of "federal law," the Act's knowingly requirement, which applies to that vague term, does not cure the Act's unconstitutional vagueness.

c. Plaintiffs' Alternative Argument Regarding the Construction of the Act Cannot Save the Act from Unconstitutionality

The Court is not persuaded by Plaintiffs' alternative argument that the Court could save the Act by construing the Act to do "nothing more than incorporate into the Ohio code the specific requirements imposed by federal law on prescribers of mifepristone, including the eight requirements set forth in the FDA Approval letter." (Doc. #69 at 17.) In so arguing, Plaintiffs necessarily conclude that the Approval letter itself has a clear meaning. As explained above, the Court disagrees.

The Court is well aware of the Supreme Court's directive that "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." See

Chapman v. U.S., 500 U.S. 453, 464 (1991). However, the Supreme Court has also explained that while the "canon of construction that a court should strive to interpret a statute in a way that will avoid an unconstitutional construction is useful in close cases . . . it is not a license for the judiciary to rewrite language enacted by the legislature." Id. (citations omitted).

This is not a close case. Here, despite having reviewed and re-reviewed the Act, the Court finds that Plaintiffs' alternative interpretation of the Act is no more reasonable (nor unreasonable) than Defendants'. Indeed, the Court finds that several other interpretations of the Act are also plausible. As such, the Court cannot agree that Plaintiffs' reading of the statute "would cure the constitutional defects created by the State's extreme interpretation," (id. at 18.). The Court would have to rewrite language enacted by the legislature to give the Act one definite meaning. The Court therefore holds that the statute cannot be saved from unconstitutionality by Plaintiffs' alternative argument.

B. No Portion of the Act is Severable and the Act Must be Enjoined in its Entirety

Because the Court has determined that summary judgment should be granted to Plaintiffs and that a permanent injunction of the Act is necessary, the Court need not consider Plaintiffs' alternative argument regarding the appropriate scope of the *preliminary* injunction. However, the Court must still consider the appropriate scope of the *permanent* injunction. See Ayotte, 126 S.Ct at 967. As the Ayotte Court explained, "when confronting a constitutional flaw in a statute, we try to limit the solution to the problem. We prefer, for example, to enjoin only the unconstitutional applications of the statute while leaving other applications in force." The Ayotte Court also pointed out that in so doing, "a court cannot 'use its remedial powers to circumvent the intent of the legislature.'" Id. at 968.

Thus, this Court must determine whether there are constitutional portions of the Act that may remain in force. See id. at 967. As the Court has determined that the Act's criminal provisions are unconstitutionally vague in all of their potential applications, the only question that remains is whether the Act's physician qualifications, recordkeeping and reporting requirements are severable from the remainder of the requirements. In so deciding, the Court must remain mindful that [its] constitutional mandate and institutional competence are limited," and "restrain [itself] from 'rewrit[ing] state law to conform it to constitutional requirements' even as we strive to salvage it." Id. at 968.

The question of whether portions of the Act can be severed from the Act's unconstitutional portions is a question of Ohio law. See Leavitt v. Jane L., 518 U.S. 137, 139 (1996). The Court must remain mindful that [its] constitutional mandate and institutional competence are limited," and "restrain [itself] from 'rewrit[ing] state law to conform it to constitutional requirements' even as we strive to salvage it." Id. at 968.

The Act itself contains no severability provision. Ohio Revised Code § 1.50, however, provides:

> If any provision of a section of the Revised Code or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the section or related sections which can be given effect without the invalid provision or application, and to this end the provisions are severable.

Ohio Rev. Code § 1.50. Thus, in Ohio, there is a presumption of statutory severability. Id.; see also Women's Med. Prof. Corp. v. Voinovich, 130 F.3d 187, 202 (6th Cir. (Ohio) 1997). Ohio courts employ the following test for determining whether an unconstitutional provision may in fact be severed:

> (1) Are the constitutional and the unconstitutional parts capable of separation so that each may read and may stand by itself? (2) Is the unconstitutional part so connected with the general scope of the whole as to make it impossible to give effect to the apparent intention of the Legislature if the clause or part is stricken out? (3) Is the insertion of words or terms necessary in order to separate the constitutional part from the unconstitutional part, and to give effect to the former only?

Women's Med. Prof. Corp. v. Voinovich, 130 F.3d at 202.

Defendants argue that the Act's physician qualifications and recordkeeping and reporting requirements can be severed from the rest of the Act and therefore should not be enjoined. Plaintiffs counter that those portions of the Act cite to, and therefore are inextricably bound up with, the portion of the Act that is unconstitutionally vague. Plaintiffs conclude that the recordkeeping and reporting requirements as well as the physician qualifications are therefore also unenforceable and must be enjoined.

The Act's physician qualification requirement provides that: "[n]o person shall knowingly . . . prescribe RU-486 (mifepristone) . . . unless the person . . . is a physician . . . satisfy[ing] *all the criteria established by federal law*." Ohio Rev. Code. § 2919.123(A) (emphasis added). The Act's reporting and recordkeeping provisions provide: [i]f a physician provides RU-486 (mifepristone) to another for the purpose of inducing an abortion *as authorized under division (A)"* of the Act, the physician must report to the state medical board certain serious health events suffered by his patient following her use of mifepristone, id. at § 2919.123(C)(1) (emphasis added), and that "[n]o physician who provides RU-486 (mifepristone) to another for the purpose of inducing an abortion *as authorized under division (A)* of [the Act] shall knowingly fail to file a report required under division (C)(1)." Id. at § 2919.123(C)(2)

(emphasis added).

It is clear that the Act's physician qualifications and recordkeeping and reporting requirements are dependent upon, and therefore inextricably bound up with, the unconstitutional portions of the Act found in § 2919.123(A) and (F)(1). As such, these requirements are not capable of separation so that each may read and may stand by itself. See Women's Med. Prof. Corp. v. Voinovich, 130 F.3d at 202. The Court therefore holds that no portion of the Act may be severed and that the Act must be enjoined in its entirety.

IV. CONCLUSION

Having found as a matter of law that the Act is unconstitutionally vague and that no portion of it can be severed, the Court hereby: 1) **GRANTS** Plaintiffs' Motion for Summary Judgment and Permanent Injunction or, in the Alternative, Renewed Motion for Preliminary Injunction (doc. #69) in so far as it requests summary judgment on the vagueness issue; and 2) **PERMANENTLY ENJOINS** Defendants from enforcing any provisions of the Act.

IT IS SO ORDERED.

s/Susan J. Dlott
Susan J. Dlott
United States District Judge